CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 086457 All Supplements

Trade Name : EPIFOAM

Generic Name: Hydrocortisone Acetate 1% and Pramoxine Hydrochloride 1%

Sponsor : Schwartz Pharma

Approval Date: Numerous

OCT 31 1980

NDA 86-457/S-001

Reed & Carnrick Pharmaceutical
Attention: Dr. Fred J. McIlreath
30 Boright Avenue
Kenilworth, NJ 07033

Gentlemen:

Reference is made to your supplement dated May 5, 1980 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (Hydrocortisone Acetate Aerosol Foam, 1%).

Reference is also made to your communication dated October 14, 1980 amending the supplement.

The supplemental application provides for as an alternate supplier of Hydrocortisone Acetate, USP.

We have completed the review of this supplemental application and it is approved. Our letter of December 19, 1979 detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 10/31/80

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

NWK-DO DUP HFD-614
HFD-616
JLMeyer/CMSmith
R/DinitJMeyer/MSeife
ft/cjl/10-30-80 approved
C.M. Smith 10-29-80
JMeyer 10/30/80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

805 amuse

To : HFD- 530
ATTN: CHIEF CHEMIST

Date: 3/10/83

FROM : Manufacturing Review Branch (HFD-324)
Division of Drug Quality Compliance

FDA Control # DD30277

SUBJECT: Expiration Date Request for GWQAP: NDA/ANDA # 86-457/S001

Drug: HYDROCORTISONE ACETATE (1 PCT) & PRAMOXINE HCL (1 PCT) AEROSOL, 10 GM (ADM)

Contractor: REED & CARNRICK, NEW ENGLAND AVE. PISCATAWAY, NJ

Container/Closure Requested:

Requested Expiration Date MAXIMUM months or maximum firm can support.

Manufacturer: SAME AS FIRM

Packager: SAME AS FIRM

Raw Material Suppliers:

Please call RIEHAN RHINEHART at x36007 immediately, if your response will be delayed past the indicated due date, or if the information available is not sufficient to complete a response.

RESPONSE DUE
3/14/83

Have response hand carried to Room 9B09 and placed in tray marked "Stability Responses" located on cabinet against wall.

STABILITY DATA SUPPORTS:

Maximum Exp. Date (mos)	Container/ Closure System	Package Size
24	[illegible]	[illegible]

Comments:

cc: HFD-324 (GWQAP)
HFD-324
HFD-

Prepared by: N. Sud for E. Serruto
Date: 3/10/83

Form FDA 3112 (2/82)

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Statement Date:

NDA # 86-457/S-001: S-002

NAME AND ADDRESS OF APPLICANT:

Reed & Carnrick Pharmaceuticals

Kenilworth, NJ 07033

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

Additional suppliers of active ingredient:

DATE(s) of SUBMISSION(s)

5/5/80; 9/3/80

10/14/80

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
glucocorticoid	Hydrocortisone Acetate	RX _____ OTC _____
DOSAGE FORM	POTENCY(IES)	RELATED IND/NDA/DMF
foam	1%	
STERILIZATION	SAMPLES	

LABELING

BIOLOGIC AVAILABILITY

ESTABLISHMENT INSPECTION

Both ~~foreing~~ foreign firms in compliance, memo dated October, 1980 from HFD-322

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

satisfactory

PACKAGING

STABILITY:

Protocol:

Exp. Date:

REMARKS & CONCLUSION:

approval

CMSmith

C.M. Smith 10-29-80

Drug

REED & CARNRICK
Pharmaceuticals
Kenilworth, New Jersey 07033 (201) 272-6600

Fred J. McIlreath, Ph.D.
VICE PRESIDENT
CLINICAL & REGULATORY AFFAIRS

October 14, 1980

5/001

Department of Health, Education and Welfare
Food and Drug Administration
Division of Generic Drug Products
5600 Fishers Lane
Rockville, MD 20852

RE: NDA 86-457
Epifoam

Gentlemen:

On May 5, 1980 we submitted a supplement to the above mentioned NDA. The purpose of this supplement was to provide for an alternate source of supply for the active ingredient, hydrocortisone acetate. In reviewing our records, we have discovered that the supplier identified in that supplement is incorrect. The correct supplier should be:

Sincerely yours,

Fred McIlreath

FJMcI:mp

REED & CARNRICK
Pharmaceuticals
Kenilworth, New Jersey 07033 (201) 272-6600

May 5, 1980

Fred J. McIlreath, Ph.D.
VICE PRESIDENT
CLINICAL & REGULATORY AFFAIRS

NDA NO. 86-457 SEQ. NO. 5/001
Suppl

Department of Health, Education & Welfare
Food & Drug Administration
Division of Generic Drug Products
5600 Fishers Lane
Rockville, MD 20852

Re: NDA 86-457
Epifoam

Gentlemen:

The purpose of this communication is to supplement the above mentioned NDA. This supplement consists of the addition of an alternate source of supply of the active ingredient, hydrocortisone acetate USP. The new supplier will be
The material supplied by
meets all the USP compendial specifications.

Sincerely yours,

Fred McIlreath

FJMcI:lh

OCT 31 1980

NDA 86-457/S-002

Reed- & Carnrick Pharmaceuticals
Attention: Dr. Fred J. McIlreath
30 Boright Avenue
Kenilworth, NJ 07033

Gentlemen:

Reference is made to your supplement dated September 3, 1980 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (Hydrocortisone Acetate Aerosol Foam, 1%.

The supplemental application provides for an alternate supplier of

We have completed the review of this supplemental application and it is approved. Our letter of December 19, 1979 detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 10/31/80

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

NWK-DO DUP HFD-614 HFD-616
JLMeyer/CMSmith
R/DinitJMeyer/MSeife
ft/cjl/10-30-80 approved

C.M. Smith 10-30-80
J.L. Meyer 10/31/80

REED & CARNRICK
Pharmaceuticals
Kenilworth, New Jersey 07033 (201) 272-6600

Drug

September 3, 1980

Fred J. McIlreath, Ph.D.
VICE PRESIDENT
CLINICAL & REGULATORY AFFAIRS

86457 Supplement 1002

Department of Health, Education & Welfare
Food & Drug Administration
Division of Generic Drug Products
5600 Fishers Lane
Rockville, MD 20852

Re: NDA 86-457
Epifoam

Gentlemen:

The purpose of this communication is to supplement the above mentioned NDA. This supplement consists of the addition of an alternate source of supply of the active ingredient, hydrocortisone acetate USP. The new supplier will be . The material supplied by meets all the USP compendial specifications.

Sincerely yours,

Fred J McIlreath

FJMcI:lh

JUL 9 1981

NDA 86-457/S-004

Reed & Carnrick Pharmaceuticals
Attention: Dr. Fred J. McIlreach
30 Bolight Avenue
Kenilworth, NJ 07033

Gentlemen:

Reference is made to your supplement dated January 23, 1981, regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (Hydrocortisone Acetate Aerosol Foam), 1%.

The supplemental application provides for a change in specifications of the product to accomodate a metered valve.

We have completed the review of this supplemental application and it is approved. Our letter of December 19, 1979, detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seife 7/9/81

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc:
NWK-DG
HFD-616
JLMeyer/CMSmith
R/D init JLMeyer/MSeife/7/8/81
pb/7/8/81
3354E

CM Smith 7-8-81
JLMeyer 7/8/81

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Statement Date:

NDA # 86-457/S-003,S-004

NAME AND ADDRESS OF APPLICANT:

Reed & Carnrick
Kenilworth NJ 07033

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

S-003..alternate mfg/supplier

S-004..a package change, use of a metered valve

DATE(s) of SUBMISSION(s)

S-003..11/18/80
S-004..1/23/81

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
glucocorticoid	Hydrocortisone Acetate	RX XXXX OTC ____
DOSAGE FORM: Foam	POTENCY(IES): 1%	RELATED IND/NDA/DMF
STERILIZATION	SAMPLES	

LABELING

NA

BIOLOGIC AVAILABILITY

NA

ESTABLISHMENT INSPECTION

NEVER INSPECTED...S. Fishman...HFD-322

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Controls are satisfactory for S-004

PACKAGING

STABILITY:

Protocol:

Exp. Date:

REMARKS & CONCLUSION:

S-003...alternate manufacturer/packager to be ..no record of inspection. Request full address and specific function. S-004..Use of a metered valve.

S-003..rev. w/f
S-004..approved

CMSmith

C M Smith 7-8-81

Drug

REED & CARNRICK
Pharmaceuticals
Kenilworth, New Jersey 07033 (201) 272-6600

Fred J. McIlreath, Ph.D.
VICE PRESIDENT
RESEARCH & DEVELOPMENT

January 23, 1981

"SPECIAL NEW DRUG APPLICATION SUPPLEMENT - CHANGES BEING EFFECTED."

Department of Health, Education and Welfare
Food and Drug Administration
(HFD-106)
5600 Fishers Lane
Rockville, MD 20852

86-457 5/200
Pka Orig

RE: NDA 86-457/S-004

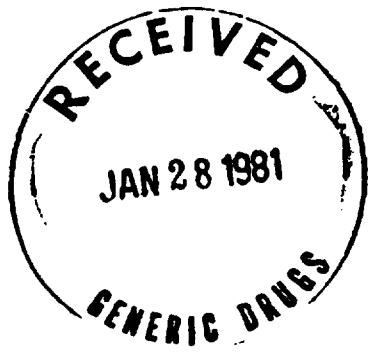
Gentlemen:

The purpose of this communication is to supplement the above mentioned drug application. This supplement, which is being submitted under the provision of §314.8(d), consists of a change in specifications of the product to accommodate a metering valve in place of the original free flowing valve. This change is not made to insure a precise dosage rather it is intended to provide an interrupted flow of medication. We learned early after introduction of this product that many people applied an excessive amount of medication before they could release the valve. This resulted in a small number of dosages per can and with a resultant high cost per dose to the patient. We believe that the use of the interrupted flow valve will allow much better control and be a significant savings to patients.

Sincerely yours,

Fred J McIlreath

FJMcI;mp
encl. (3)



SEP 1 1982

NDA 86-457/S-005

Reed and Carnrick Pharmaceuticals
Attention: Robert J. Mandetta
One New England Avenue
Piscataway, New Jersey 08854

Gentlemen:

Reference is made to your supplement dated July 9, 1982, regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (Hydrocortisone Acetate Aerosol Foam), 1%.

The supplemental application provides for a change in your manufacturing facilities from the location to

We have completed the review of this supplemental application and it is approved. Our letter of December 19, 1979 detailed the conditions relating to the approval of this application.

The material submitted is being retained as part of your application.

Sincerely yours,

Marvin Seife 9/1/82

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of The Associate Director
for Drug Monographs
Office of Drugs
National Center for Drugs and Biologics

cc: NWK-DO
HFD-616
HFD-530
HFD-534 (H. Zell) 8/31/82
HZell/BTArnwine B.T. Carnwine
R/D INITIAL HZell/MSeife
mstephens: 8/31/82 (8291A) H.C. Zell 8/31/82
Approved

NDA 86-457 CHEMIST'S REVIEW FOR ANDA OR SUPPLEMENT

NAME AND ADDRESS OF APPLICANT:
Reed and Carnrick
Piscataway, New Jersey 08854

PURPOSE OF AMENDMENT/SUPPLEMENT
S-005 Manufacturing facility change

DATE(S) OF SUBMISSION(S)
7/9/82

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
Glucocorticord	Hydrocortisone Acetate (Epifoam)	RX

DOSAGE FORM	POTENCY	STERILIZATION
Aerosol	1%	NA

SAMPLES
NA

LABELING
NC

BIOLOGIC AVAILABILITY
NA

ESTABLISHMENT INSPECTION
Firm is changing their manufacturing facility from the
to Satisfactory, as per
Seymour Fishman 8/20/82.

STABILITY
Commitment is made to place first three batches on stability at 3 month intervals the first year, 6 month intervals the second year and yearly intervals thereafter.

REMARKS AND CONCLUSION
S-005 Approved

Brenda T. Arnwine

Brenda T. Arnwine
8/31/82
JACzell 8/31/82

REED & CARNRICK
Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
MANAGER REGULATORY AFFAIRS

July 9, 1982

Department of Health and Human Services
Food and Drug Administration
HFD-106
5600 Fishers Lane
Rockville, Maryland 20852

NDA NO. 16457 REF. NO. 005
NDA SUPPL FOR [illegible]

RE: EPIFOAM NDA 86-457/S-005

Gentlemen:

The purpose of this communication is to supplement the above mentioned drug application. This supplement, which is being submitted under the provision of section 314.8(a)(4), consists of changes in manufacturing facilities. The new headquarters of REED & CARNRICK will provide additional space to allow increased segregation of manufacturing and anticipated future growth.

Previously approved equipment and methods that were employed in our Kenilworth location will be utilized in our new facility.

Stability studies on the first three batches will be submitted at intervals of three months beginning with the date of initial packaging during the first year following such date, at intervals of six months during the second year following such date, and at yearly intervals thereafter for as long as necessary to support an assigned expiration date.

Current component specifications have been included in this submission. These component specifications now reflect current USP and NF nomenclature.

All other documents that have been affected by any changes in specification nomenclature are also enclosed. All changes are compendial, not procedural.

The completion of our manufacturing facilities is anticipated by August 2, 1982. However, due to possible scheduling conflicts, we would prefer to notify the Agency by telephone as to when we would be operational and available for inspection. Please do not schedule an inspection prior to receiving telephone notification from REED & CARNRICK.

RECEIVED
JUL 13 1982
GENERIC DRUGS

Sincerely yours,

RJM:mp
encl.

NDA 86-457/S-006

AUG 20 1984

Reed & Carnrick Pharmaceuticals
Attention: Robert Mandetta
One New England Avenue
Piscataway, New Jersey 08854

Gentlemen:

Reference is made to your supplement dated March 17, 1983 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (Hydrocortisone acetate 1% and pramoxine hydrochloride 1%) Aerosol Foam.

Reference is also made to your communication(s) dated October 13, 1983, April 19, 1984 and August 9, 1984 amending this supplement.

The supplemental application provides for revised package insert.

We have completed the review of this supplemental application and it is approved. Our letter of December 19, 1979 detailed the conditions relating to the approval of this application.

The material submitted is being retained in our files.

Sincerely yours,

Kjw Johnson /for 8-20-84

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

cc:
NWK-DO
HFN-230
HFN-83
HFW-20
MSeife/KJohnson/mk/8/17/84
4883A

APPROVAL

Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
MANAGER REGULATORY AFFAIRS

Draft copy is satisfactory
Prepare FPL.
5-8-84

April 19, 1984

Food and Drug Administration
Division of Generic Drug Monograph
HFD-530
Room 16-69
5600 Fishers Lane
Rockville, Maryland 20857

NDA SUPPL AMENDMENT
S-00[illegible]
DRAFT LABELING

RE: EPIFOAM
NDA 86-457/S-009

Gentlemen:

Reference is made to your letter of December 8, 1983 concerning our supplement of October 13, 1983. The comments of your December 8, 1983 correspondence have been incorporated into our labeling.

Upon reviewing the class labeling for this drug, we are recommending some minor revisions. Some are grammatical changes and others, in our opinion, better define the statement they are intended to make.

For your convenience, two sets of draft labeling are enclosed. One set is the original, the second set has all the proposed changes highlighted.

Sincerely yours,

RJM:mp
encls.

APR 27 1984

NDA 85-457/S-006

DEC 8 1983

Reed & Carnrick Pharmaceuticals
Attention: Robert J. Mandetta
One New England Avenue
Piscataway, NJ 08854

Gentlemen:

Reference is made to your supplement dated March 17, 1983 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) Aerosol Foam.

Reference is also made to your letter of October 13, 1983 amending this supplement.

The supplemental application provides for revised package insert labeling.

We have reviewed the draft copy submitted and have the following recommendations for revision:

1. TITLE: (non-proprietary name to read:)

   (hydrocortisone acetate 1% and pramoxine hydrochloride 1% topical aerosol)

2. Nursing Mothers: The terminology of the Class Labeling Guideline is preferrable. The study presented to support your statement is not clearly indicative of quantities which may be found in breast milk. We note that the study subjects were 7 healthy males.

3. Also: Include name and place of business of the manufacturer.
   Also: Revised, Month/Year.

Please incorporate the above comments into your labeling, then prepare and submit twelve final printed copies when available.

Sincerely yours,

Marvin Seife 12/8/83

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
National Center for Drugs & Biologics

NWK-DO
HFN-530 12/7/83
KJohnson/MSeife
ft/cjl/12-7-83
rev w/f

APR 7 1983

NDA 86-457/S-006

Reed & Carnrick
Attention: Robert J. Mandetta
One New England Avenue
Piscataway, NJ 08854

Gentlemen:

Reference is made to your supplement dated March 17, 1983 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epifoam (hydrocortisone acetate aerosol foam), 1%.

The supplemental application provides for revised package insert labeling.

We have reviewed the draft copy submitted and have the following comments:

TITLE: You must include Pramoxine Hydrochloride as an active ingredient if you wish to note these in the title.

DESCRIPTION: You must note pramoxine hydrochloride as an active ingredient. Likewise, its structural formula should be presented.

CLINICAL PHARMACOLOGY: Include a brief statement relating to pramoxine.

INDICATIONS: (delete)... of the anogenital region.
OR ..... (revise to) .... of the anal area.

Nursing Mothers: we suggest the terminology of the Class Labeling Guideline.

DOSAGE AND ADMINISTRATION:

Note the frequency of administration.

CAUTION: Delete "a".

Please revise your insert labeling as described above, then prepare and submit draft copy for our review and comment.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife 4/7/83

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of the Associate Director for
Drug Monographs
Office of Drugs
National Center for Drugs & Biologics

cc:
NWK-DO
HFN-530
KJohnson/MSeife
ft/cjl/4-5-83
rev w/f

REED & CARNRICK
Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
MANAGER REGULATORY AFFAIRS

March 17, 1983

Division of Generic Drug Monographs
Food and Drug Administration
Room 16-69
HFD-530
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 86-457 REF. NO. S-006
NDA SUPPL FOR Labeling

RE: EPIFOAM 86-457/S-006

Gentlemen:

DRAFT LABELING

The purpose of this communication is to supplement the above referenced drug application. This supplement, which is being submitted under section 314.8(a)(4)(i), consists of revised labeling reflecting the labeling format revisions of Federal Register 44:37434 June 26, 1979.

Pursuant to your request of February 4, 1982, this labeling is submitted as a draft copy.

Sincerely yours,

RJM:mp
encl.(3)

RECEIVED
MAR 31 1983
GENERIC DRUGS

ANDA 86-457/S-007

Reed & Carnrick Pharmaceuticals
Attention: Robert J. Mandette
One New England Avenue
Piscataway, New Jersey 08854

DEC 9 1985

Dear Mr. Mandette:

Reference is made to your supplemental new drug application submitted pursuant to Section 314.70 of the Regulations, dated March 20, 1985 regarding your abbreviated new drug application for EPIFOAM (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) Aerosol Foam.

The supplemental application provides for the use of

as

an alternate packager of the finished dosage form.

We have completed the review of this supplemental application and it is approved. Our letter of December 19, 1979 detailed the conditions relating to the approval of this abbreviated application.

The material submitted is being retained as part of your application.

Sincerely yours,

Robert G. Johnson for 12-9-85

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

cc: NWK-DO
HFN-83
HFN-230
HFN-234
HCZell/BTArnwine
R/D INITIALED BY HCZell/MSeife
mstephens: 12/6/85 (0930s)
Approval

12/9/85 B T Arnwine

HC Zell 12/9/85

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA NUMBER: 86-457

NAME AND ADDRESS OF APPLICANT

Reed & Carnrick Pharmaceutical Inc.
Randolph, Massachusetts 08854

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

DATE(s) of SUBM.:

PURPOSE OF AMENDMENT/SUPPLEMENT

S-007-Alternate package

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
Glucocorticoid	EPIFOAM (hydrocortisone acetate and pramoxine hydrochloride)	RX X OTC
DOSAGE FORM(S)	POTENCY(IES)	RELATED IND/NDA/DM
Foam	1%	
STERILIZATION	SAMPLES	

LABELING

NC

BIOLOGIC AVAILABILITY

N/A

ESTABLISHMENT INSPECTION

Firm wishes to use as an alternate packager of the finished product. Packager is satisfactory as per J.J.Christeson 11/22/85

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

NC

PACKAGING

NC

STABILITY
Protocol:

NC

Exp. Date:

REMARKS AND CONCLUSION: First inspection request was lost.

S-007 Approval

TBC per JJC
12/5/85

JJC
12/4/85

NDA 86-457/S-007

Reed & Carnrick Pharmaceuticals, Inc.
Attention: Robert J. Mandetta
One New England Avenue
Piscataway, NJ 08854

[redacted] 28 1985

Dear Mr. Mandetta:

Reference is made to your supplement dated March 20, 1985 regarding your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for EPIFOAM (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) Aerosol Foam.

The supplemental application provides for the use of

as an alternate packager of the finished dosage form.

We have reviewed the material submitted and have the following comments:

We are awaiting the evaluation of the above packager for Good Manufacturing Practices compliance by the Division of Drug Quality Compliance. We will communicate with you upon completion of the evaluation.

Please let us have your response promptly.

Sincerely yours,

Marvin Seife 8/28/85

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

cc:
NWK-DO 8/27/85
HFN-230
HFN-234 B Kenwine Johnson 8-28-85
HCZell/BTArnwine/KJohnson 8/27/85 HC. Zell
R/D INITIALED:HCZell/MSeife
mk:8/26/85:0477m

RWF

REED & CARNRICK
Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
MANAGER REGULATORY AFFAIRS

March 20, 1985

Food and Drug Administration
Division of Generic Drug Monographs
HFD-530
Room 16-69
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 86-457 REF. NO. 5007
NDA SUPPL FOR PKah

RE: EPIFOAM
NDA 86-457/S-012

Gentlemen:

The purpose of this communication is to supplement the above mentioned drug application. This supplement consists of an alternate packager of the finished dosage form. The name and address of the packager is as follows:

Bulk finished product along with approved cans and valves are shipped to the packager, aerosolized and returned to Reed and Carnrick for labeling packaging and testing as described in our approved application.

A letter of authorization to their Drug Master File is enclosed.

Sincerely yours,

R. Mandetta

RJM:el
encls.

RECEIVED
MAR 26 1985
GENERIC DRUGS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

TO :Manufacturing Review Branch (HFN-322) DATE: 11/12/85
Division of Drug Quality Compliance

FROM :Division of Generic Drugs HFN-234
Requester's Name Brenda T. Arnwine PHONE:443-1390

SUBJECT: ESTABLISHMENT EVALUATION REQUEST

NDA, ANDA, AND SUPPLEMENT NUMBER: 86-195/S-020 and 86-457/S-007

DRUG TRADE MARK (if any) _____

DRUG NONPROPRIETARY NAME: Hydrocortisone Acetate 1% and Pramoxine Hydrochloride 1%

DOSAGE FORM AND STRENGTH(S): Foam

DRUG CLASSIFICATION:
(Priority) _____ A or B _____ 1C _____ Other X

PROFILE CLASS CODE: ADM

APPLICANT'S NAME: Reed & Carnrick Pharmaceuticals
ADDRESS: Piscataway, New Jersey 08854

FACILITIES TO BE EVALUATED: (Name, Full Address, DMF# (if any), and Responsibility)

— Alternate packager

—

—

Comments: ( ) See Attached.
( ) Actual on-site inspection requested.

Reason: _____

****

FOR HFN-322 USE ONLY:

Request Rec'd: _____ Inspection Requested: _____
(if applicable)

Firm(s) are in Compliance With GMPs: _____
Basis for Decision: _____
Reviewing CSO: _____ Concurrance: _____

cc: HFN-____
HFN-____
HFN-322

FORM FDA 3274 (1/83)

REED & CARNRICK
Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
MANAGER REGULATORY AFFAIRS

October 13, 1983

Division of Generic Drug Monographs
Food and Drug Administration
Room 16-69
HFD-530
5600 Fishers Lane
Rockville, Maryland 20857

NDA SUPPL AMENDMENT
006
DRAFT LABELING

RE: EPIFOAM NDA-86-457/S-007

Gentlemen:

Reference is made to your letter of April 7, 1983 regarding revised packaging insert labeling for the above referenced drug.

This supplement consists of revised draft labeling pursuant to your request of April 7, 1983.

Enclosed is data in support of the statement found in the "Nursing Mothers" section of our labeling.

Sincerely yours,

RJM:mp
encl.

Orig-

REED & CARNRICK
Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
DIRECTOR REGULATORY AFFAIRS

September 5, 1986

Food and Drug Administration
Division of Generic Drug Monographs
HFD-530
Room 16-69
5600 Fishers Lane
Rockville, Maryland 20857

SUPPL NEW CORRES
NAT
1334
12/9/86

RE: EPIFOAM
ANDA 86-457/S007
Amendment 001

Gentlemen:

Reference is made to your letter of December 9, 1985 regarding the above mentioned ANDA, EPIFOAM. This letter approved the use of

as an alternate packager of the finished dosage form.

This address is not the correct address of the actual facility. The correct address, which was inspected by the FDA, is:

Sincerely yours,

RJM:mm

RECEIVED
SEP 10 1986
GENERIC DRUGS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

TO :Manufacturing Review Branch (HFN-322) DATE: 8/20/85
Division of Drug Quality Compliance

FROM :Division of Generic Drugs HFN-234
Requester's Name Brenda T. Arnwine PHONE: 443-1390

SUBJECT: ESTABLISHMENT EVALUATION REQUEST

NDA, ANDA, AND SUPPLEMENT NUMBER: 86-457/S-007

DRUG TRADE MARK (if any) EPIFOAM

DRUG NONPROPRIETARY NAME: Hydrocortisone Acetate 1% and Pramoxine Hydrochloride 1%

DOSAGE FORM AND STRENGTH(S): Aerosol foam

DRUG CLASSIFICATION: PROFILE CLASS CODE:
(Priority) ____ A or B____ 1C____Other__X__ ADM____

APPLICANT'S NAME: Reed & Carnrick Pharmaceuticals
ADDRESS: Piscataway, New Jersey 08854

FACILITIES TO BE EVALUATED: (Name, Full Address, DMF# (if any), and Responsibility)

Alternate packager

Comments: ( ) See Attached.
( ) Actual on-site inspection requested.

Reason:

FOR HFN-322 USE ONLY:

Request Rec'd:_____ Inspection Requested:_____
(if applicable)

Firm(s) are in Compliance With GMPs:_____
Basis for Decision:_____
Reviewing CSO:_____ Concurrance:_____

cc: HFN-____
HFN-____
HFN-322

FORM FDA 2374 (1/83)

ANDA 86-457/S-010

Reed & Carnrick Pharmaceuticals
Attention: Richard K. Bourne, Ph.D.
257 Cornelison Avenue
Jersey City, NJ 07302-3198

NOV 16 1994

Dear Sir:

This is in reference to your supplemental new drug application dated May 19, 1994, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug application for Epifoam® (Hydrocortisone Acetate 1% and Pramoxine Hydrochloride 1% Topical Foam).

The supplemental application provides for the

as an additional stability testing site and as an alternate testing site for product release.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

RKPatel 11/15/94

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

REED & CARNRICK
Pharmaceuticals
Piscataway, New Jersey 08854 (201) 981-0070

Robert J. Mandetta
MANAGER REGULATORY AFFAIRS

Orig

August 9, 1984

NDA SUPPL AMENDMENT

Food and Drug Administration
Division of Generic Drug Monographs
HFD-530
Room 16-69
5600 Fishers Lane
Rockville, MD 20857

EPI

RE: EPIFOAN
NDA 86-457/S-010

Gentlemen:

Reference is made to your letter of December 8, 1983 and our submission of April 19, 1984. Enclosed are 12 final printed copies.

Sincerely yours,

RJ Mandetta

RJM:ml
encls.

AUG 13 1984

EP281E84

Epifoam®

(hydrocortisone acetate 1% and pramoxine hydrochloride 1% topical aerosol)

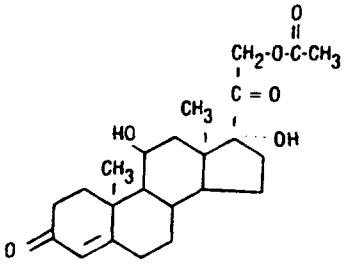
DESCRIPTION:

A topical corticosteroid in an aerosol foam containing hydrocortisone acetate 1% and pramoxine hydrochloride 1% in a base containing: propylene glycol, cetyl alcohol, glyceryl stearate, PEG-100 stearate, laureth-23, polyoxyl-40 stearate, methylparaben, propylparaben, trolamine or hydrochloric acid to adjust pH, purified water, propellants (inert): butane and propane.

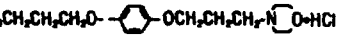
EPIFOAM® contains a synthetic steroid used as an anti-inflammatory and anti-pruritic agent, and a local anesthetic.

Molecular weight: Hydrocortisone acetate 404.51. Solubility of hydrocortisone acetate in water: 1 mg/100ml.

Chemical name: Pregn-4-ene, 3,20-dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11β).



Pramoxine Hydrochloride



CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

PRAMOXINE HYDROCHLORIDE

A surface or local anesthetic which is not chemically related to the "caine" types of local anesthetics. Its unique chemical structure is likely to minimize the danger of cross-sensitivity reactions in patients allergic to other local anesthetics.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase the percutaneous absorption of topical corticosteroids. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See DOSAGE AND ADMINISTRATION.)

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS AND USAGE:

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNING:

Not for prolonged use. If redness, pain, irritation or swelling persists, discontinue use and consult a physician. Contents of the container are under pressure, but not flammable. Do not burn or puncture the aerosol container. Store at temperatures below 120°F. Keep this and all medicines out of the reach of children.

PRECAUTIONS:

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steriods, use over large surface areas, prolonged use and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary hydrocortisone and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

In children absorption may result in higher blood levels and thus more susceptibility to systemic toxicity. (See PRECAUTIONS — Pediatric Use.)

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Do not use this medication for any disorder other than for which it has been prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Report any signs of local adverse reactions especially under occlusive dressings.
5. Do not use tight fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests

The following tests may be helpful in evaluating the HPA axis suppression:

Urinary hydrocortisone test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been performed to evaluate carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity wih prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women of teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Caution should be exercised when any topical corticosteroids are administered to a nursing woman.

Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisone levels and absense of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

Burning	Allergic contact dermatitis
Itching	Maceration of the skin
Irritation	Secondary infection
Dryness	Skin atrophy
Folliculitis	Striae
Hypopigmentation	Miliaria
Perioral dermatitis	

OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS.)

DOSAGE AND ADMINISTRATION:

Apply to affected area 3 or 4 times daily.
(NOTE: Refer to the enclosed Directions for Use.):

DIRECTIONS FOR USE:

1. Shake foam container vigorously before use.
2. Hold container upright and dispense medication onto a pad by depressing the container cap several times. A small amount of foam is all that is needed on the pad. Apply to affected areas.
   Alternatively, the foam may be applied directly to affected areas.
3. The container and cap should be disassembled and rinsed with warm water after use.

NOTE: The aerosol container should never be inserted into the vagina or anus.

HOW SUPPLIED

EPIFOAM® (NDC 0021-0740-10) available in 10g pressurized cans.

CAUTION:

FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.

REED & CARNRICK
1 New England Avenue
Piscataway, NJ 08854

Revised April 1984

OFFICE OF GENERIC DRUGS

CHEMISTRY, MANUFACTURING, AND CONTROLS:

REVIEW OF SUPPLEMENTAL APPLICATION

ANDA 86-195/SC023
86-457/SC010

Chemist's Review # 1

NAME AND ADDRESS OF APPLICANT:

Reed & Carnrick Pharmaceuticals
Attention: Richard K. Bourne
257 Cornelison Avenue
Jersey City, NJ 07302-3198

PURPOSE OF AMENDMENT/SUPPLEMENT

To provide for Analytical Testing Laboratories of the Block Drug Company, in Jersey City, which will serve as an additional stability testing site, and as an alternate testing site for product release.

DATE(S) OF SUBMISSION(S)

05/19/94

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
An anti-inflammatory and antipruritic agent, and a local anesthetic.	86-195: Proctofoam-HC 86-457: Epifoam	Hydrocortisone acetate and Pramoxine HCl

DOSAGE FORM	POTENCY	RX OR OTC
86-195: Topical aerosol	1%/1%	Rx
86-457: Topical foam	1%/1%	Rx

SAMPLES	RELATED IND/NDA/DMF	STERILIZATION
N/A	N/A	N/A

LABELING N/A

BIOEQUIVALENCE STATUS N/A

Reviewer	Date Completed
Eugene L. Schaefer, Ph.D.	11/8/94
Endorsed by P.Schwartz, Ph.D.	11/9/94

ESTABLISHMENT INSPECTION

GMP certification letters from are provided.

EERs have been submitted. The address of the facility to be inspected is:

Block Drug Company, Inc.
257 Cornelison Avenue
Jersey City, NJ 07302

The inspection should cover laboratories for chemical, physical, and microbiological testing, plus stability storage chambers.

The facility was found acceptable on 10/21/94.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Validation reports for the assay of hydrocortisone acetate and pramoxine hydrochloride, in concentrates and in the final products, are provided.

PACKAGING N/A

STABILITY

Stability protocols are provided.

"All stability samples for ANDA approved marketed product will be physically transferred to and maintained in the Block Drug Company, Jersey City storage chamber(s)."

"Testing will be performed at either the Reed & Carnrick, Piscataway facility or the Block Drug Company, Jersey City facility."

REMARKS AND CONCLUSION

The supplements are **APPROVABLE.**

RECALLS N/A

ORDER OF REVIEW

The application submission covered by this review was taken in the date order of receipt: Yes____X____ No_____

If no, explain reason(s) below:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

Original ✓

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE (Check)	DATE	PHONE NO.	EER ID #
☒ Original ☐ FollowUp ☐ FUR	July 18, 1994	594-1844	EE21

REQUESTORS NAME: Gene Schaefer	DIVISION: Office of Generic Drugs	MAIL CODE: HFD-629

APPLICATION AND SUPPLEMENT NUMBER: ANDA 86-195/SC-023

BRAND NAME: Proctofoam-HC	ESTABLISHED NAME: Hydrocortisone Acetate 1% and Pramoxine Hydrochloride 1% Topical Aerosol
DOSAGE STRENGTH: 1%/1%	STERILE ☐Yes ☒ No
PROFILE CLASS:: ADM	PRIORITY CLASSIFICATION (STG M CDER-4820.3)

APPLICANT'S NAME: Reed & Carnrick Pharmaceuticals

APPLICANT'S ADDRESS: 257 Cornelison Avenue
Jersey City, NJ 07302-3198

COMMENTS :The supplement provides for a laboratory which will serve as an additional site for stability testing and as an alternate site for product release testing. The inspection should cover chemical, physical, and microbiological laboratories, and stability storage chambers.

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY	
1. Analytical Testing Laboratories Block Drug Company 257 Cornelison Avenue Jersey City, NJ 07302-3198	Stability and product release testing.	NEC	1C685 BLDJ	AR	10/5/94 NAI

FOR HFD-324 USE ONLY:	CSO Shirrette Burgess	DATE RECEIVED 9/2/94
	CGMP COMPLIANCE STATUS acceptable	DATE 10/21/94

FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
NDA 86-195 HFD-629/Div File, HFD-617/JWilson, HFD-617/JDawson, HFD-629/PSchwartz, HFD-629/ELSchaefer

REED & CARNRICK
PHARMACEUTICALS

257 Cornelison Avenue Jersey City, N.J. 07302-3198
Telephone (201) 434-3000
FAX (201) 434-0842

Research and Development Laboratories

RICHARD K. BOURNE, Ph.D.
Vice President - Regulatory Affairs

NDA NO. _____ REF. NO. 5010
NDA SUPPL FOR Fourth Amd

NEXT DAY AIR

May 19, 1994

Douglas Sporn, M.D.
Director
Division of Generic Drug Products
HFD-600, Document Control Room #17B-20
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: ANDA #86-457 EPIFOAM

Supplement to an Approved Application

Dear Dr. Sporn:

Pursuant to 21 CFR 314.70 (b)(2)(iv) and (vi), we are submitting the enclosed supplement to the subject ANDA which provides for an additional stability testing site for Epifoam.

Currently, Reed and Carnrick (Division of Block Drug Company), Piscataway, New Jersey is the approved site where stability testing and release are conducted.

We propose to add the Analytical Testing Laboratories of the Block Drug Company, 257 Cornelison Avenue, Jersey City, N.J., as an additional site where stability testing will be conducted. These laboratories will also serve as an alternate testing site for product release.

The following documents are included to support this supplement:

1. GMP certification letter for the Block Drug Company.

2. Proposed stability protocol (#320-008A). This protocol will become effective following approval and transfer of the stability program to the Block Drug Company.

3. Methods validation report (#VAL-0040A) for hydrocortisone acetate and pramoxine hydrochloride generated by the Analytical Testing Laboratories at Block Drug Company to support testing of Epifoam at this facility.

4. Approved test method (430N-0068A) for hydrocortisone acetate and pramoxine hydrochloride in the concentrate.

5. Approved test method (#420N-534A) for hydrocortisone acetate and pramoxine hydrochloride in the finished product.

A completed Form 356h, Form 3397 and an index is enclosed herein.

Should you have any questions, please do not hesitate to contact me at (201) 434-3000; ext. 1995.

Sincerely,

Richard K. Bourne

Richard K. Bourne

Enclosures
Submission in Duplicate
Acknowledgement Copy
Copy sent to:
Ms. H. Pederson
Newark District Office

ANDA 86-457/S-013

Schwarz Pharma, Inc.
Attention: Steven R. Pollock
P.O. Box 2038
Milwaukee, WI 53201

FEB 28 1997

Dear Sir:

This refers to your supplemental new drug application dated February 7, 1996, submitted pursuant to 21 CFR 314.70 for Epifoam® (Hydrocortisone Acetate and Pramoxine Hydrochloride Topical Aerosol, 1%/1%).

The supplemental application provides for an alternate finished product release site and a change of the stability testing site to SPInc, Milwaukee, WI.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

2/28/97

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS

CHEMISTRY, MANUFACTURING, AND CONTROLS:

REVIEW OF SUPPLEMENTAL APPLICATION

ANDA 86-457/SC013 Chemist's Review # 1

NAME AND ADDRESS OF APPLICANT:

Schwarz Pharma, Inc.
Attention: Steven R. Pollock
P.O. Box 2038
Milwaukee, WI 53201

PURPOSE OF AMENDMENT/SUPPLEMENT

To provide for an alternate finished product release site and a change of the stability testing site to SPInc, Milwaukee, WI.

DATE(S) OF SUBMISSION(S)

02/07/96

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
An anti-inflammatory and antipruritic agent, and a local anesthetic.	Epifoam	Hydrocortisone acetate and Pramoxine HCl

DOSAGE FORM	POTENCY	RX OR OTC
Topical aerosol	1%/1%	Rx

SAMPLES	RELATED IND/NDA/DMF	STERILIZATION
N/A	ANDA 86-195: Proctofoam-HC (Topical aerosol)	N/A

Supplement 86-195/SC025 requests a similar change and is being reviewed concurrently. Separate reviews are being written because 86-195/SC025 and 86457/SC013 contain different documents.

LABELING N/A

BIOEQUIVALENCE STATUS N/A

ESTABLISHMENT INSPECTION

An EER was submitted on 9/11/96. The facility was found to be **acceptable** on 1/30/97.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Components, composition and manufacturing remain unchanged.

The following controls information is provided:

Schwarz Pharma, Inc. (SPInc) Test Method - Hydrocortisone Acetate and Pramoxine Hydrochloride Assays

Method Validation - Cross-lab study to demonstrate lab-to-lab equivalency between Block Drug and Schwarz Pharma

Block Drug Co. Analytical Test Methods - Determination of Hydrocortisone Acetate and Pramoxine Hydrochloride in concentrate and in marketed container

Validation Report for Block Drug Co. Analytical Test Methods

SPInc Drug Product Specification

These are **satisfactory.**

PACKAGING N/A

STABILITY

The following stability information is provided:

SPInc Stability Protocol

Additional SPInc Stability Methods

These are **satisfactory.**

REMARKS AND CONCLUSION

The supplement can be **APPROVED.**

RECALLS N/A

ORDER OF REVIEW

The application submission covered by this review was taken in the date order of receipt: Yes___X_____ No_____

If no, explain reason(s) below:

SCHWARZ
PHARMA

February 7, 1996

Charles Ganley, M. D., Director
Office of Generic Drugs
Document Control Room 150
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

NDA NO. _____ REF. NO. SC013
NDA SUPPL FOR Control Rec

RECEIVED
FEB 08 1996
GENERIC DRUGS

RE: EPIFOAM® topical aerosol (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) ANDA 86-457

SUPPLEMENT 013
CMC - Stability Testing Site Change

Dear Dr. Ganley:

Pursuant to 21 CFR § 314.70(b), Schwarz Pharma, Inc. (SPInc) hereby submits Supplement 013 to ANDA 86-457 to provide for an alternate finished product release site and a change of the current stability testing site from Block Drug Company, Inc., Jersey City, New Jersey, to SPInc, Milwaukee, Wisconsin. Transfer of ownership of the above-referenced ANDA from Block Drug Co., Inc. to SPInc was effective July 11, 1995.

This statement will certify that a true and complete copy of this submission has been forwarded to the Minneapolis District Office of the Food and Drug Administration.

Please note that effective August 29, 1995, Schwarz Pharma Kremers Urban Company officially and legally became registered as Schwarz Pharma, Inc. Any future correspondence concerning this application will be under the new corporate name. If there are any questions regarding this submission, please contact Susan K. Nunchuck-Schumski, Ph.D., Manager, Regulatory Affairs, at (414) 238-5474.

Sincerely,

SCHWARZ PHARMA, INC.

Steven R. Pollock
Director, Regulatory Affairs

Copies to: R. Bourne and J. Lee, Block Drug Co., Inc.

Mail P.O. Box 2038 · Milwaukee, WI 53201 · 5600 W. County Line Road · Mequon, WI 53092
Phone 414-354-4300 · Telex 4311043 · Fax 414-354-4309

ANDA 86-457/S-014

Schwarz Pharma, Inc.
Attention: Steven R. Pollock
P.O. Box 2038
Milwaukee, WI 53201

SEP 25 1996

Dear Sir:

This is in reference to your supplemental new drug application dated May 13, 1996, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug application for Epifoam® (Hydrocortisone Acetate and Pramoxine Hydrochloride Topical Aerosol, 1%/1%).

Reference is also made to your amendment dated August 14, 1996.

The supplemental application provides for a change in the filling and packaging site to

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

DSGrill for 9-23-96

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS

CHEMISTRY, MANUFACTURING, AND CONTROLS:

REVIEW OF SUPPLEMENTAL APPLICATION

ANDA 86-457/SC014 Chemist's Review # 1

NAME AND ADDRESS OF APPLICANT:

Schwarz Pharma, Inc.
Attention: Steven R. Pollock
P.O. Box 2038
Milwaukee, WI 53201

PURPOSE OF AMENDMENT/SUPPLEMENT

To provide for a change in the filling and packaging site to .

DATE(S) OF SUBMISSION(S)

05/13/96 Submitted - Expedited Review requested
05/20/96 Expedited Review denied
06/17/96 The facility was found to be acceptable.
08/14/96 Gratuitous amendment - stability data

PHARMACOLOGICAL CATEGORY	TRADE NAME	NONPROPRIETARY NAME
An anti-inflammatory and antipruritic agent, and a local anesthetic.	Epifoam	Hydrocortisone acetate and Pramoxine HCl

DOSAGE FORM	POTENCY	RX OR OTC
Topical aerosol	1%/1%	Rx

SAMPLES	RELATED IND/NDA/DMF	STERILIZATION
N/A	ANDA 86-195: Proctofoam-HC (Topical aerosol) See DMF Checklist.	N/A

A similar change is not being requested for 86-195 at this time.

LABELING N/A

BIOEQUIVALENCE STATUS N/A

ESTABLISHMENT INSPECTION

The facility was found to be acceptable on 6/17/96 (EER ID# . The EER is in the jacket.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

There is no change in components, composition, manufacturing, or controls. DP specs, and DP CoA are provided.

PACKAGING

There is no change in container or closure. Pages 5 to 7 show that the filling operations at the approved site and at the proposed site are equivalent. Blank and executed filling records are provided.

STABILITY

Stability protocols were provided on 5/13/96. Stability results for 3 months RT and 1, 2, and 3 months accelerated were provided on 8/14/96. RT = 25°C ± 2°C/60%RH ± 5%RH. Acc = 40°C/75%RH.

results are not provided because this test is only performed annually for RT and after 6 months accelerated. However, acceptable initial results for bacterial count, mold count, and absence of pathogens were provided on 5/13/96, and primary container integrity results conform with specs.

The stability data are acceptable.

REMARKS AND CONCLUSION

The supplement can be **APPROVED.**

RECALLS N/A

ORDER OF REVIEW

The application submission covered by this review was taken in the date order of receipt: Yes_____ No___X_____

If no, explain reason(s) below:

The submission was more than 90 days old and was reviewed in conjunction with 86-457/SC013, which was taken in the date order of receipt.

DMF CHECKLIST FOR ANDA/AADA #86-457/SC014 REVIEW # 1

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED

Comments:

Aerosol filling of drug product.
2

Comments:

Comments:

Comments:

Comments:

Comments:

Comments:

Comments:

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:
(2) Type 1 DMF; (3) Reviewed previously and no relevant revision since last review;
(4) Sufficient information in application; (5) Authority to reference not granted;
(6) DMF not available; (7) Other (explain under"Comments").

Checklist page 1 of 1 . Eugene L. Schaefer E L Schaefer 9/13/96

Reviewer Signature Date

SCHWARZ
PHARMA

August 14, 1996

RECEIVED
AUG 15 1996
GENERIC DRUGS

Douglas Sporn, M.D., Director
Office of Generic Drugs
Document Control Room 150
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

SUPPL AMENDEMENT
SC-014/AC

RE: ANDA 86-457; EPIFOAM® topical acrosol
(hydrocortisone acetate 1% and pramoxine hydrochloride 1%)

AMENDMENT 001 to SUPPLEMENT 014 - CMC - Stability Data

Dear Dr. Sporn:

Pursuant to 21 CFR § 314.70(b), Schwarz Pharma, Inc. (SPInc) hereby submits Amendment 001 to Supplement 014 to the above-referenced ANDA. Supplement 014, submitted May 13, 1996, requested a change in the filling and packaging site for Epifoam topical aerosol from To support the site change, accelerated and controlled room temperature stability testing on the lots used in the filling operation at was initiated in April with the commitment to provide data to the agency as soon as available. The stability data is provided herein.

SPInc requested expedited review of Supplement 014 to permit uninterrupted flow of this drug product to the marketplace.

This statement will certify that a true and complete copy of this submission has been forwarded to the Detroit and the Minneapolis District Offices of the Food and Drug Administration.

If there are any questions regarding this correspondence, please contact Elaine Cibulka, Associate Manager, Regulatory Affairs, at (414)238-5454.

Sincerely,

SCHWARZ PHARMA, INC.

Elaine Cibulka for

Steven R. Pollock
Director of Regulatory Affairs

Mail P.O. Box 2038 · Milwaukee, WI 53201 · 5600 W. County Line Road · Mequon, WI 53092
Phone 414·354·4300 · Telex 4311043 · Fax 414·354·4309

SCHWARZ
PHARMA

NDA NO. _____ REF. NO. 5014
NDA SUPPL FOR ~~Facility Add.~~ Scale Up

May 13, 1996

Douglas Sporn, M.D., Director
Office of Generic Drugs
Document Control Room 150
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

RECEIVED
MAY 14 1996
GENERIC DRUGS

RE: ANDA 86-457; EPIFOAM® topical aerosol
(hydrocortisone acetate 1% and pramoxine hydrochloride 1%)

SUPPLEMENT 014 - CMC - Filling/Packaging Site Change

EXPEDITED REVIEW REQUESTED

Dear Dr. Sporn:

Pursuant to 21 CFR § 314.70(b), Schwarz Pharma, Inc. (SPInc) hereby submits Supplement 014 to ANDA 86-457 to provide for a change in the filling and packaging site for Epifoam topical aerosol from

Epifoam topical aerosol was recently purchased from Block Drug Company, with transfer of ownership completed on July 11, 1995. There is an immediate need to qualify a new filler for the product, as the previous filler for this drug product is no longer able to perform the filling operation. This supplement is a site change for the filling and packaging only; there has been no change in manufacture of the concentrate, product ingredients, the propellant, or the components. SPInc requests expedited review of this supplement to permit uninterrupted flow of this drug product to the marketplace.

This statement will certify that a true and complete copy of this submission has been forwarded to the Detroit and the Minneapolis District Offices of the Food and Drug Administration.

If there are any questions regarding this correspondence, please contact Elaine Cibulka, Associate Manager, Regulatory Affairs, at (414)238-5454.

Sincerely,

SCHWARZ PHARMA, INC.

Elaine Cibulka for

Steven R. Pollock
Director, Regulatory Affairs

5-17-96

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